

## **REMARKS**

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1 and 3-13 are pending in this application. Claim 7 has been withdrawn from consideration and claims 1 and 8-13 are currently under examination. (New claims 11-13 have been added which are similar to claims 6-8, but are ultimately dependent upon claim 3 rather than claim 1). No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. THE OBJECTIONS TO THE SPECIFICATION HAS BEEN OVERCOME**

The specification was objected to for the use of the term “ormocer” alleging that it is being used as a trademark. However, this is incorrect because the applicants are not using the term ormocer as a trademark and relying on a meaning which consistent with that recognized in the art.

The term ormocer is also widely equated with the term “inorganic-organic composites” (see Publication of the DITC, Accession No. AD P006430 and WO 1995-013855 - page 1, line 12 – copies enclosed with this response) and “hybrid materials containing organic-inorganic units” (see A. Doraiswamy et al., “Biocompatibility of CAD/CAM Ormocer Polymer Scaffold Structures”, published by the Materials Research Society – copy enclosed with this response) which is consistent with the definition being applied by the applicants in this application (see e.g. the Abstract – “...with at least one layer consisting of an inorganic-organic hybrid polymer (Ormocer)).

The applicants further show that the term is not being used as a trademark in that the term ormocer is not referred to in all capital letters nor is the <sup>TM</sup> or ® symbol used when using this term.

### **III. THE 35 U.S.C. 112, 2<sup>nd</sup> PARAGRAPH REJECTION HAS BEEN OVERCOME**

Claims 1-6 and 8-10 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. The applicants request reconsideration of this rejection for the following reasons.

With regard to claims 1 and 9, the term “readily” has been deleted.

Claim 8 has been amended to delete the phrase “in each case”. With regard to the nature of the surfaces, one of ordinary skill in the art would recognize this to refer to the top and bottom surfaces of the supporting layer.<sup>1</sup> However, if this is the only issue precluding allowance of the claim, the Examiner is authorized to prepare an Examiner’s amendment to replace the term “both” with ---top and bottom---.

The claims were also rejected as using a trademark, however, as explained above in II., the applicants are not using the term as a trademark.

### **IV. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME**

A. Claims 1, 2, 4-6 and 8 were rejected as allegedly being obvious by Kwiatek et al. (US 4,710,191 - “Kwiatek”) in view of Amberg-Schwab et al. (*J. Sol-Gel Sci and Tech*; Jan 2003, cited on PTO-1449 - “Amberg”). The applicants request reconsideration of this rejection for the following reasons.

Establishing obviousness requires that all claim limitations be taught or suggested by the prior art reference or by teachings generally known within the art. In this regard the applicants agree with the assertion that Kwiatek does not disclose or suggest the use of inorganic-organic copolymers (ormocers) as a suitable material for their outer backing layer (110) or the backing layer (106). However, the combination with Amberg does not serve to remedy the deficiency of the Kwiatek reference.

Amberg is directed to inorganic-organic polymers as migration barriers against liquid and volatile compounds in the context of products useful in the food *packaging* or pharmaceutical

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<sup>1</sup> “The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, *not whether more suitable language or modes of expression are available*. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define with a *reasonable* degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. *Examiners are encouraged to suggest claim language to applicants to improve clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.*” See MPEP 2173.02.

packaging industry (see page 699, col. 1, last four lines thru col. 2, first two lines), i.e. represents a teaching away from the transdermal devices such as that claimed by the applicants or referred to in Kwiatek. The beneficial effects of the inorganic-organic polymers of Amberg attributed in the Office Action, e.g. protection against steaming, no electrostatic charging, etc. (see page 703, col. 1 (paragraph 3.2) and col. 2, paragraph 4), are within the context of using these polymers for packaging products not for a transdermal device.

Moreover, for the claims as amended, the covering film of the applicants' claims surprisingly maintained both a barrier effect properties AND elastic properties. The combination of Kwiatek and Amberg neither teaches or suggests that such a combination would have both properties (which is shown by the applicants in Figure 2 (nicotine uptake shows the effectiveness of the covering film as a barrier) and Figure 3 (shows that elasticity did not affect nicotine uptake)).

To the contrary, Amberg's direction toward packaged products suggests a teaching away by providing a barrier effect with *inelastic* properties. This is borne out in the applicants specification which refers to several patents which teach the use of ormocers (see paragraph [0015] from the publication of this application) which date from the mid-1990s and yet no reference has been cited which shows the applicants covering layer for a transdermal device.

Therefore, the applicants' claimed invention is not obvious over the combination of Kwiatek and Amberg as there was no motivation to combine the respective teaching or reasonable expectation of success that the combination would result in a covering layer with suitable barrier effect and elasticity as required for a transdermal device.

**B. Claims 1, 3, 9 and 10 were rejected as allegedly being obvious by Kwiatek and Amberg as applied to claims 1, 2, 4-6 and 8 above, and further in view of Osborne et al. (US 5,004,610 - "Osborne").** The applicants request reconsideration of this rejection for the following reasons.

The applicants' response above in A. is applicable here as claims 3, 9 and 10 are ultimately dependent on claim 1.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
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